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TXR-6169

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

006169

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SEP 2 1986

SUBJECT: EPA Registration No. 476-859
Vapam Soil Fumigant Solution For All Crops

FROM: Mary L. Waller
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C)

MW
E 9/22/86

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

APPLICANT: Stauffer Chemical Company
1200 South 47th Street
Richmond, CA 94804

ACTIVE INGREDIENT:
Sodium methyldithiocarbamate. 32.7%
INERT INGREDIENTS: 67.3%

BACKGROUND:

The registrant has submitted an acute inhalation, acute oral, acute dermal, primary skin, and primary eye irritation study. The studies were conducted by Stauffer Chemical Company. The data Accession Number is 263846. The method of support is owner submission.

RECOMMENDATION:

FHB/TSS finds the data on Vapam Technical acceptable to support registration of Vapam (Registration No. 476-859) since the registrant has specified in the data package that the two products are synonymous. The signal word is "WARNING."

The Product Manager should inform the registrant that when conducting acute dermal toxicity studies, the LD_{50} for each sex should be provided.

The registrant must submit a dermal sensitization study if this data requirement has not been satisfied.

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LABELING:

1. Provide information or data to support the current Statement of Practical Treatment for oral exposure or revise the Statement as follows:

   IF SWALLOWED: Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

2. Place Storage and Disposal instructions under Directions For Use immediately following the misuse statement or at the end of the Directions For Use.

3. Delete the following two sentences from the Precautionary Statements: Do not store near food or feed. Keep children and pets out of treated area.

REVIEW:

(1) Acute Inhalation Toxicity Study: Stauffer Chemical Company, Richmond Toxicology Laboratory Inhalation Facility; Study No. T-6457; June 1, 1979.

PROCEDURE:

Ten male and ten female Sprague-Dawley rats were exposed for 4 hours in a 447 stainless steel and glass inhalation chamber to an aerosol generated from test material. The gravimetric concentration ranged fom 4.3 to 5.1 mg/L (mean concentration = 4.7 mg/L). Animals were observed twice daily for 14 days. Animals were weighed on the day of exposure and on days 3, 8, and 14. All animals were necropsied.

RESULTS:

One out of ten male rats died. The LC_{50} was reported to be > 4.7 mg/L. Toxic symptoms observed were depression, blood-like stains about the face, dyspnea and prostration. Gross necropsy of males revealed reddish brown and grayish brown foci on lung lobes and dilation of the renal pelvis of the right kidney. No compound-related abnormalities were noted in the females.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

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(2) Acute Oral Toxicity Study: Stauffer Chemical Co.; Richmond Toxicology Laboratory; Report No. T-11494; January 17, 1985.

PROCEDURE:

Groups of 10 male and 10 female Sprague-Dawley rats were administered a single oral dose of test material suspended in water as follows: male groups received 2239, 1778, 1413, 1259, 1122, or 891 mg/kg and female groups received 2239, 1778, 1584, 1500, 1413, or 891 mg/kg. A control group of 60 male and 60 female rats were dosed with water. Animals were observed for 14 days and necropsied at study conclusion.

RESULTS:

At 2239 mg/kg, 10/10 males and 10/10 females died. At 1778 mg/kg, 8/10 males and 10/10 females died. At 1584 mg/kg, 7/10 females died. At 1500 mg/kg, 9/10 females died. At 1413 mg/kg, 6/10 males and 3/10 females died. At 1122 and 891 mg/kg, no deaths occurred. The LD_{50} for males was reported to be 1294 mg/kg (95% confidence limits = 1062-1578 mg/kg). The LD_{50} for females was reported to be 1428 mg/kg (95% confidence limits = 1352-1508 mg/kg).

Toxic symptoms included depression, clonic and tonic convulsions, loss of righting reflex, hypersensitivity, ptosis, salivation, piloerection, reddish limbs, swollen eyes, ataxia, stained fur, hunched posture, facial stains, dyspnea, anogenital stains, lacrimation, chromodacryorrhea, excessive urination and tremors. Gross necropsy revealed reddened lungs, clear fluid in thoracic cavity, test material-like fluid in the stomach, pale liver, darkened liver, gelatinous-appearing intestines, reddish fluid in the bladder, pale kidneys, pale intestines, mottled lungs, darkened spleen, reddened stomach mucosa, yellowish-red fluid in the intestines, engorged blood vessels on the stomach, solid material in bladder and kidney, enlarged hollowed kidneys, reddened or thickened bladder walls, white spots on kidneys, bloated gastrointestinal tract, darkened thymuses, distended stomachs, pale uteri, opaque eyes, and enlarged and darkened adrenals.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

(3) Acute Dermal Toxicity Study: Stauffer Chemical Co.; Richmond Toxicology Laboratory; Report No. T-11494; January 17, 1985.

PROCEDURE:

Albino rabbits were clipped closely on the abdomin and received dermal applications of test material under occlusive wrap for 24 hours of exposure as follows: one group of five males and five females received 2000 mg/kg and three groups of four males and four females received 1584, 1259, or 794 mg/kg. After exposure, the wrap and residual material were removed. Irritation was observed and test site was rewrapped in gauze for 3 days. Animals were observed for 14 days and all animals were necropsied upon discovery of death or at study conclusion.

RESULTS:

At 2000 mg/kg, 9/10 animals. At 1584 mg/kg, 6/8 died. At 1259 mg/kg, 6/8 died. No deaths occurred at 794 mg/kg. The LD_{50} was reported to be 1012 mg/kg (95% confidence limits = 720-1421 mg/kg).

Toxic symptoms observed were severe depression, ataxia, prostration, and shallow respiration. Gross necropsy revealed reddened or pale lungs, mottled livers, darkened or dark-edged spleens, pale spleens, distended gallbladders, yellowish fluid in the intestines, reddened stomach mucosa, small gallbladder, darkened spots on the stomach mucosa, pale uterine horns, and darkened thymus.

STUDY CLASSIFICATION:

Core Minimum Data - See comments under Recommendation.

TOXICITY CATEGORY: Category II - WARNING.

(4) Primary Skin Irritation Study: Stauffer Chemical Co.; Richmond Toxicology Laboratory; Report No. T-11494; January 17, 1985.

PROCEDURE:

Six albino rabbits received 0.5 ml of test material applied to one abraded and one intact skin test site/animal. The test sites were kept under occlusive wrap for 4 hours. Skin irritation was scored upon removal of wrap and at 24 and 72 hours.

RESULTS:

Skin irritation was scored as follows: at 24 hours, animals exhibited erythema ranging from well-defined to severe and edema ranging from moderate to severe; and at 72 hours,

5/6 animals exhibited severe erythema, 1/6 animals exhibited moderate to severe erythema, 4/6 animals exhibited moderate edema and 2/6 animals exhibited very slight edema. At 72 hours, 1/6 animals exhibited severe eschar formation. On day 7, all animals exhibited darkened test sites, eschar formation and superficial sloughing at test sites.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category II - WARNING.

(5) Primary Eye Irritation Study: Stauffer Chemical Co.; Richmond Toxicology Laboratory; Report No. T-11494; January 17, 1985.

PROCEDURE:

Nine albino rabbits were examined using fluorescein dye to ensure that they were free of any ocular injury or irritation. Twenty-four hours later each animal received 0.1 ml of test material which was instilled in the conjunctival sac of the left eye. The treated eye of 3/9 animals was washed with water 20 to 30 seconds after exposure. The untreated eye of each animal served as a control. Eye irritation was scored at 1, 24, 48, and 72 hours and at 4 and 7 days. Treated eyes were tested with fluorescein stain at 24 hours after exposure and until there was no staining for three consecutive observations.

RESULTS:

Eye irritation in the unwashed group was scored as follows: at 24 hours, conjunctiva redness (1/6) and at day 2, all irritation had cleared. Eye irritation in the washed group was scored as follows: at 1 hour, conjunctivae redness (1/6 = 2, 2/6 = 1), and chemosis (1/6 = 2, 1/6 = 1) and at 24 hours, all irritation had cleared.

STUDY CLASSIFICATION: Core Guideline Data.

TOXICITY CATEGORY: Category III - CAUTION.

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